Question Paper

Exam Date & Time: 13-May-2023 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Regulatory Aspects of Herbal and Biologicals [PRM-MRA202T -S1]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1)	Discuss the USFDA Code of Federal Regulations for Current Good Manufacturing Practice for Finished Pharmaceuticals with respect to biologicals.	(10)
2)	Explain the regulatory requirements for marketing authorization of similar biologics in India.	(10)
3)	Explain the procedure for registration of vaccines in India.	(10)
4)	Explain the preclinical safety evaluation guideline for biotechnology products as applicable in European Union.	(10)
5)	Compare the herbal products regulations in India, USA and European Union.	(10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6)	In case of an adverse drug reaction due to similar biologics, discuss about the Risk Management Plan as per CDSCO guideline.	(5)
7)	Define the term "Interchangeability" and write a short note on FDA perspective on interchangeability.	(5)
8)	Explain the procedure of Plasma Master File Certification.	(5)
9)	List out and explain various regulatory agencies for vaccine registration in India.	(5)
10)	Is Biosimilar same as generics? Justify your answer.	(5)

-----End-----